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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,844	08/18/2003	Alfred J. Lewy	90,559-T	3196

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EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 09/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/642,844	LEWY ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-24 are presented for examination.

Requirement for Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 12, drawn to a method of treating jet lag comprising the administration of melatonin, melatonin agonist or compound that increases endogenous production of melatonin in humans according to the steps of claims 1-8 and 11, classified in class 514, subclass 419 (melatonin *per se*), for example, depending on the agent used.

II. Claim 13, drawn to a method of treating winter depression comprising the administration of melatonin, melatonin agonist or compound that increases endogenous production of melatonin in humans according to the steps of claims 1-8 and 11, classified in class 514, subclass 419 (melatonin *per se*), for example, depending on the agent used.

III. Claims 14-16, drawn to a method of treating a sleep disorder comprising the administration of melatonin, melatonin agonist or compound that increases endogenous production of melatonin in humans according to the steps of claims 1-8 and 11, classified in class 514, subclass 419 (melatonin *per se*), for example, depending on the agent used.

IV. Claim 17, drawn to a method of treating free-running circadian rhythm disorder comprising the administration of melatonin, melatonin agonist or compound that increases endogenous production of melatonin in humans according to the steps of claims 1-8 and 11, classified in class 514, subclass 419 (melatonin *per se*), for example, depending on the agent used.

V. Claim 19, drawn to a method of treating jet lag comprising the administration of melatonin, melatonin agonist or compound that increases endogenous production of melatonin in humans according to the steps of claims 9-10 and 18, classified in class 514,

subclass 419 (melatonin *per se*), for example, depending on the agent used.

VI. Claim 20, drawn to a method of treating winter depression comprising the administration of melatonin, melatonin agonist or compound that increases endogenous production of melatonin in humans according to the steps of claims 9-10 and 18, classified in class 514, subclass 419 (melatonin *per se*), for example, depending on the agent used.

VII. Claims 21-23, drawn to a method of treating a sleep disorder comprising the administration of melatonin, melatonin agonist or compound that increases endogenous production of melatonin in humans according to the steps of claims 9-10 and 18, classified in class 514, subclass 419 (melatonin *per se*), for example, depending on the agent used.

VIII. Claim 24, drawn to a method of treating free-running circadian rhythm disorder comprising the administration of melatonin, melatonin agonist or compound that increases endogenous production of melatonin in humans according to the steps of claims 9-10 and 18, classified in class 514, subclass 419 (melatonin *per se*), for example, depending on the agent used.

Claims 1-8 and 11 link Inventions I-IV and claims 9-10 and 18 link Inventions V-VIII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-8 and 11 or claims 9-10 and 18. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction

requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. Please reference *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP §804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions I through VIII are patentably distinct. Inventions are patentably distinct if it can be shown that they have different modes of operation, different functions, or different steps, effects and different resultant endpoints (See MPEP § 806.04, MPEP § 808.01). In the instant case, it is noted that the ultimate therapeutic objective of, for example, Invention I (i.e., treating jet lag) is distinct from the therapeutic objective of, for example, Invention II (e.g., treating winter depression) and that the steps and effects required for the execution of any one of Inventions I-IV is distinctly different than those required for the execution of any one of Invention V-VIII.

Inventions I through VIII are held to be patentably distinct because the treatment of Invention I would not necessarily result in the treatment of any one or more of Inventions II-VIII. The patient populations in which each method would be practiced are distinctly different (e.g., patients suffering from jet lag versus patients suffering from winter depression), such that the treatment of one patient population would not necessarily suggest, anticipate or render obvious the treatment of the other patient population. While there may be incidental overlap in the groups of patients experiencing, for example, jet lag, and those experiencing, for example, winter depression, the endpoints and steps required to treat such conditions are vastly different and do not reasonably suggest, anticipate or render obvious the treatment of the other.

Furthermore, the dosage amounts or frequency and route of administration necessary to effect the treatment of patients with, for example, jet lag, would necessarily be independent and distinct from that required for the treatment of patients with, for example, winter depression, due to the differences in etiology of such a condition and the activity of the claimed agent(s) in treating such a condition. Moreover, one skilled in the art could practice the invention of any one of Inventions I through VIII

without practicing any one or more of the other inventions. Thus, Inventions I through VIII are properly considered patentably distinct from one another.

Because these inventions are independent or distinct for the reasons given above, they require a different field of search (see MPEP § 808.02) and they have acquired a separate status in the art because of their recognized divergent subject matter, the requirement for election for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though this requirement be traversed (37 C.F.R. 1.143) and (ii) an identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should Applicant traverse on the ground that the inventions or species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie A. Royds
Patent Examiner
Art Unit 1614

September 21, 2006

9/23/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER